



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/099,898	06/18/1998	KARIN FRANZ-BACON	DX0744K	7975

28008 7590 12/31/2001

DNAX RESEARCH INSTITUTE
LEGAL DEPARTMENT
901 CALIFORNIA AVENUE
PALO ALTO, CA 94304

EXAMINER

WEGERT, SANDRA L

ART UNIT	PAPER NUMBER
----------	--------------

1647

DATE MAILED: 12/31/2001

ib

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/099,898

Applicant(s)

FRANZ-BACON ET AL.

Examiner

Sandra Wegert

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-26,28 and 30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-26,28 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 19-26,28 and 30 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Status of Application, Amendments, and/or Claims

The amendment filed 15 Oct 2001 (Paper No. 15) has been entered in full. Claims 27 and 29 are canceled. Claims 19-26, 28 and 30 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections And/Or Rejections

The rejection of claim 27 under 35 U.S.C. 101 as set forth at p 5 of the previous Office Action (Paper No. 13, 11 April 2001) is *withdrawn* in view of the cancelled claim (Paper No. 15, 15 October 2001).

Art Unit: 1647

The rejection of claim 19 under 35 U.S.C 112, first paragraph, as set forth on p. 8 of the previous Office Action (Paper No. 13, 11 April 2001) is *withdrawn* in view of the explanation by the applicant that the processing sites and characteristics of the "mature" polypeptide are listed in Table 1 of the specification (Paper No. 15, 15 October 2001).

The rejection of claim 27 under 35 U.S.C. 102(a) as set forth at p 10 of the previous Office Action (Paper No. 13, 11 April 2001) is *withdrawn* in view of the cancelled claim (Paper No. 15, 15 October 2001).

The rejection of claims 19-28 and 30 under 35 U.S.C 112, first paragraph, as set forth on p. 8-9 of the previous Office Action (Paper No. 13, 11 April 2001) is *withdrawn* because the structural characteristics of the polynucleotide are listed in Table 1 of the specification (Paper No. 15, 15 October 2001).

Maintained Objections And/Or Rejections

Claim Rejections - 35 USC § 101 and 35 USC § 112--first paragraph, utility/enablement

Claims 19-26, 28 and 30 are rejected under 35 U.S.C. 101 and 112, first paragraph, as lacking utility and not being enabled for lack of utility. The reasons for this rejection are set forth at pp. 3-8 of the previous Office Action (Paper No. 13, 11 April 2001).

Applicant argues (pp. 2-5, Paper No. 15, 15 October 2001) that the specification discloses an enabled utility for the current invention as to be used for diagnosis of a disease state, such as an inflammatory disease state (p. 53, for example). However, this asserted utility is not

Art Unit: 1647

substantiated by examples in the specification. The specification does not disclose a link between the claimed polynucleotide and inflammatory diseases, nor does it disclose *any* diseases associated with altered levels or forms of the polynucleotide of the claimed invention, aside from its isolation from inflamed tonsil tissue (p. 66). Numerous immunological cells that express the polynucleotide of the invention are listed, however there is no discussion of a specific disease state identified, nor data on the tissue types which do *not* express the polynucleotide. Significant further experimentation would be required of the skilled artisan to identify individuals having overexpression, underexpression or mutations in the polypeptide encoded by the claimed polynucleotide, and then correlating that deficit with a clinical syndrome that necessitates diagnosis, for example.

Furthermore, the examiner agrees that applicants are their own lexicographer, and may use the acronym *CRSP* and *Cysteine-Rich Soluble Protein* (Miyazaki, et al, 1999, J.E.M, 189:413) to name their invention (p. 2, Paper No. 15, 15 October 2001).

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1647

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

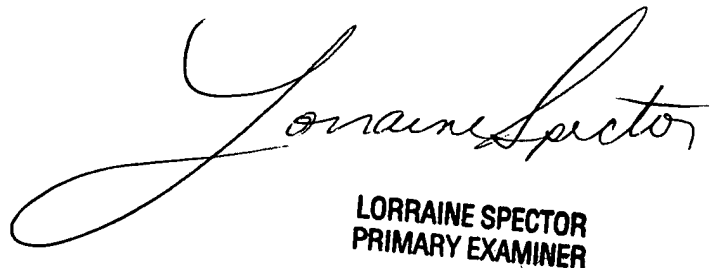
Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (703) 308-9346. The examiner can normally be reached Monday - Friday from 9:00 AM to 5:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SLW

12/26/01



LORRAINE SPECTOR
PRIMARY EXAMINER